knowledge of the FDA-approved indications of commonly prescribed drugs, and to assess whether physicians' belief that an indication is FDA-approved increases with level of evidence supporting such use. **METHODS:** We conducted a national random sample mail survey of 599 primary care physicians and 600 psychiatrists conducted from November 2007 through August 2008. Physicians were presented with 14 drug-indication pairs (e.g., gabapentin [Neurontin®] for diabetic neuropathy) that varied in their FDA-approval status and levels of supporting evidence. The main outcome measure was physicians' knowledge of whether each drug was FDA-approved for the indication in question. **RESULTS:** The adjusted response rate was 47%, and the mean (median) number of drugs examined that were prescribed during the previous 12 months was 11 (12). The average respondent correctly identified the FDA-approval status of just over half of the drug-indication pairs queried (mean 55%; median 57%). The proportion increased modestly (mean 59%, median 61%) when limited to drugs the respondent reported having prescribed during the previous 12 months. There was a strong association between physicians' belief that an indication was FDA-approved and greater evidence supporting that use (Spearman's rho 0.74, $p < 0.001$). However, 41% of physicians believed at least one drug-indication pair with uncertain or no supporting evidence (e.g., quetiapine [Seroquel®] for dementia with agitation) was FDA approved. **CONCLUSIONS:** These findings highlight an important need for more effective methods to inform physicians about the evidence base, or lack thereof, for drugs they prescribe off label.

PHP7

ABOLITION OF PRESCRIPTION CO-PAYMENTS: AN ANALYSIS OF ITEMS DISPENSED IN WALES

Hughes DA[1], Alam FM[2], Cohen D[2], Dunstan F[3], Groves S[2], Routledge PA[3]
[1]Bangor University, Bangor, UK, [2]University of Glamorgan, Pontypridd, UK, [3]Cardiff University, Cardiff, UK

OBJECTIVES: Prescription charges were abolished in Wales in April 2007. We hypothesised that as a result, the demand for prescription medicines might increase, and compared the rates of dispensing of the 15 medicines that most frequently incurred a prescription charge, versus a region with similar socio-economic characteristics that continues to charge patients (NE England). **METHODS:** Monthly data from 2002 to 2008 (one year post abolition) on the quantities of dispensed medicines were obtained from Health Solutions Wales and the Prescription Pricing Authority. Descriptive comparative analyses of unadjusted dispensing rates (per 1000 list size) were conducted for each medicine. **RESULTS:** The combined dispensing rates for all 15 medicines increased significantly in both regions, but the change in Wales was higher than that in England (Wales change = 57.67, $p < 0.0001$, 95%CI = 55.09 to 60.28; NE England change = 30.18, $p < 0.0001$, 95%CI 27.32 to 33.03). The difference between regions was statistically significant (difference = 27.51, $p < 0.0001$, 95%CI 23.66 to 31.35). Whilst an expected widening of the difference between regions was apparent for some medicines, factors beside the abolition of prescription charges are likely to account for the observed differences in others. For atenolol, a reduction in overall dispensing is observed to coincide with trial evidence that cast doubts for its suitability as a first-line drug for hypertension. The dispensing of co-codamol has risen dramatically in Wales, but not NE England, possibly related to different recommendations following the withdrawal of co-proxamol. **CONCLUSIONS:** The abolition of prescription charges is associated with changes in dispensing rates in Wales for some evaluated medicines. However, the data require to be interpreted in the context of the low proportion of prescriptions that were previously charged, and changes in clinical practice.

PHP8

A COMPARISON OF POLICIES ON PAEDIATRIC DOSING GUIDELINES AND INDICATIONS BETWEEN THE UNITED STATES AND EUROPE

Nixon F, Chan M, Lock K
Heron Evidence Development Ltd, Luton, UK

OBJECTIVES: To compare legislation on paediatric dosing guidelines and indications between the US and Europe and to examine whether the introduction of new regulations and financial incentives has resulted in more pharmaceutical companies providing paediatric data. **METHODS:** Information was extracted from published policies and reports on paediatric therapeutics as published by the US Food and Drug Administration and the European Medicines Agency. **RESULTS:** In the US, the Food and Drug Administration Modernisation Act (FDAMA; 1997) offered six months of marketing exclusivity to manufacturers voluntarily conducting paediatric studies. Current legislation in the US consists of the Best Pharmaceuticals for Children Act (BPCA; 2002), and the Paediatric Research Equity Act (PREA; 2003). Manufacturers are also encouraged to obtain orphan drug designation for drugs or biological products for use in a paediatric population. To January 2008, the FDA has sent written requests for paediatric studies to sponsors of 301 drugs. There have been 157 incidents of labeling changes under the BPCA and 76 labeling changes or submissions of supporting information under the PREA. Legislation on paediatric therapeutics was issued in the EU in January 2007 (Regulation (EC) No 1901/2006 as amended). Since this time, the EMEA has adopted decisions on 99 applications for paediatric investigational plans (PIPs) and waivers; 57 positive opinions on PIPs; 3 proposed modifications to PIPs; and 39 waivers in all age groups for all conditions. Additionally, most European Health Technology Assessment agencies do not make special allowances for the assessment of paediatric therapeutics and dosing. **CONCLUSIONS:** The introduction of legislation in the US has been successful in encouraging research into the use of therapeutics in paediatric patients. In the EU, although many applications of PIPs and waivers have been reviewed, the situation should be monitored over the coming years to determine if the legislation leads to changes.

PHP9

THE IMPACT OF LEGISLATION AND PRICING ON GENERIC DRUG UTILIZATION: AN ANALYSIS OF 26 COUNTRIES

Patorno E, Margulis A, Cai S, Gagne JJ, Geisler BP, Li Q, Lin SW, Liu W, Palmsten K, Yau WP, Polinski JM
Harvard School of Public Health, Boston, MA, USA

OBJECTIVES: Across countries with varying political, socioeconomic and cultural environments, we sought to identify predictors of generic drug utilization. **METHODS:** Data were collected from national and international regulatory agencies, MEDLINE and internet searches for 37 countries classified as "advanced" or "emerging" economies by the International Monetary Fund: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, India, Ireland, Israel, Italy, Japan, Luxembourg, Malta, Mexico, Netherlands, New Zealand, Norway, Portugal, Russia, San Marino, Singapore, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, UK, United States. We compared the presence of generic policies, first year of generic legislation, branded drug patent duration, proportion of generic drug utilization, and pricing for generics (government control, free market, or other), gross domestic product, and population across countries. Only independent variables with $p < 0.20$ in univariate regression were included in the multivariate model: population, year of generic legislation, patent life, and pricing for generics (market vs. government control). **RESULTS:** Of 37 countries, data was available for 26 (70%): Argentina, Australia, Austria, Brazil, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Portugal, Russia, Singapore, Spain, Sweden, Switzerland, UK and United States. Most countries enacted generic drug legislation in the 1990s, 9 (35%) introduced legislation before 1990, and 3 (12%) after 2000. Branded drug patent duration was 15–20 years for 65% of countries. Among countries with generic drug laws, only free market-based generic pricing, compared to government-controlled pricing, was associated with a nominal increase in generic drug utilization (B = 0.17, 95% CI −0.01, 0.35). **CONCLUSIONS:** Countries with free market pricing policies had minimally greater diffusion of generic drugs compared to countries with government pricing controls. Further investigation of other characteristics, namely the political and social climates that foster greater generic drug utilization is planned.

PHP10

CHARACTERISTICS OF MEDICARE PART-D ENROLLEES WITH AND WITHOUT PRESCRIPTION DRUG COVERAGE GAP

Said Q, Li C, Hastings J, Souder E
University of Arkansas for Medical Sciences, Little Rock, AR, USA

OBJECTIVES: To compare socioeconomic and behavioral characteristics of Medicare Part-D enrollees who reached prescription drug coverage gap (in-gap) versus those who did not (no-gap), in 2007. The study is unique because it examined characteristics of Medicare Part-D enrollees that are typically not available in administrative claims databases. **METHODS:** A survey based on the Seniors' Prescription Coverage, Use and Spending Survey and the Brief Medication Questionnaire was developed and distributed to elderly persons seeking care at the pharmacies within the University of Arkansas for Medical Sciences College of Pharmacy Advanced Community Practice Network. Patients recruited were 65 years or older, enrolled in Medicare Part D in 2007, and taking medications for any of the following conditions: hypertension, hyperlipidemia, diabetes, asthma/COPD, or depression. **RESULTS:** In this initial phase, 69 patients were enrolled and 24 (34.8%) reported reaching the coverage gap in 2007. Among in-gap patients, 95% were aged 65–85 years and 58% were female, compared to 73% and 64% respectively for the no-gap subjects. Compared with the no-gap subjects, more in-gap subjects attended college (78% vs. 46%), had a monthly income of $2000 or more (70.8% vs. 56%), and spent more than $300 per month on medications (42% vs. 24%). Compared with no-gap patients, in-gap patients were less likely (54% vs. 69%) to report overall satisfaction with Part-D programs. Finally, 87.5% of the in-gap patients reached the gap in September 2007 or later. **CONCLUSIONS:** One-third of the subjects reached the coverage gap and most of them reached the gap within the last quarter of 2007, mitigating the impact of coverage gap to some extent. The in-gap group belonged to higher socioeconomic status, which was expected since the no-gap group appeared not to be at the risk of coverage gap because of low-income subsidies. Experiencing coverage gap negatively impacted patients' satisfaction with Part-D plans.

PHP11

THE IMPACT OF NON-REFERRAL OUTPATIENT CO-PAYMENT ON MEDICAL CARE UTILISATION AND EXPENDITURE IN TAIWAN

Chen LC[1], Schafheutle E[2], Noyce P[2], Wen YH[1], Wu JS[3]
[1]Kaohsiung Medical University Hospital, Kaohsiung, Taiwan, [2]University of Manchester, Manchester, UK, [3]Bureau of National Health Insurance, Kaohsiung, Taiwan

OBJECTIVES: Taiwan's National Health Insurance's (NHI) generous coverage and patients' freedom to access different tiers of medical facilities has resulted in accelerating outpatient care utilisation and cost. To deter non-essential visits and encourage initial contact in primary care, a differential co-payment was introduced on July 15, 2005. Under this, patients pay more for outpatient consultations at higher medical facilities, particularly if accessed without referral. This study aimed to explore the impact of this policy on outpatient medical activities and expenditure, different co-payment groups and tiers of medical facilities. **METHODS:** A segmented time-series analysis on regional weekly outpatient medical claims (January 2004 to July 2006). Outcome variables (number of visits, number of outpatients, total cost of outpatient care) and variables for cost structure were stratified by tiers of medical facilities and